K062526

17.0 SMDA 510(K) SUMMARY

APR 13 2007

1.	**Applicant**	:	MULTISAFE SDN. BHD Lot 764, Bidor Industrial Estates, 35500 Bidor, Perak Darul Ridzuan, Malaysia.
	Tel No.	:	605-4348269
	Fax No	:	605-4348266
	Name of Contact Person	:	1. Mr. Abd Hadi bin Husin 2. Ms. Rosnani Binti Hassan Besari
	Date of Summary Prepared	:	28th February 2007

2. Name of Device

Trade Name	:	Blue Powdered Latex Examination Glove, Non-Sterile
Common Name	:	Examination Gloves
Classification Name	:	Patient Examination Gloves (Class 1 in US and European markets, Class IIa in Canadian Market)

3. Identification Of the Legally Marketed Devices

Latex Patient Examination Gloves LYY, Powdered that meets all the requirements of FDA, ASTM D 3578, ISO 11193, EN 455 : Part 1, Part 2 and Part 3, CMDR, MDR and CGSB.

4. **Description Of the Devices**

Latex Patient Examination Gloves, LYY, Powdered

5. **The Intended Use of Glove**

A medical glove is worn on the hands of healthcare and similar personnel as a barrier against potentially infectious materials and other contamination between healthcare and patient's body, fluid, waste or environment.

6. The Quality performance of the glove are shown in the table above meets ASTM D 3578-01 Standard and FDA's requirement

7. The Biocompatibility Test consists of Primary Dermal Irritation Study And the Dermal Sensitization Study.
The gloves pass the Biocompatibility Test.

8. Summary of Quality Performance

The Quality Performance of gloves based on the requirements stated in item 6.

TEST	REQUIREMENT	IN-HOUSE QUALITY PERFORMANCE
1. Water Leak Test (1000ml)	GII, AQL 2.5	Pass GI, AQL 1.5
2. Length (mm)		
Size : XS	Min. 220	Minimum 290 mm for all sizes
S	Min. 230	
M	Min 230	
L	Min 230	
XL	-	
3 Palm Width (mm)		
Size : XS	70±10	75-78
S	80±10	82-86
M	90±10	92-95
L	100±10	103-109
XL	-	111-115
4. Thickness (mm) (Single layer)		
Finger	Min 0.08	Min 0.10
Palm	Min 0.08	Min 0.10
5. Physical Properties		
Before Ageing		
Tensile Strength (MPa)	Min. 14	Min 18
Ultimate Elongation (%)	Min 700	Min 700
After Ageing		
Tensile Strength (MPa)	Min.14	Min. 14
Ultimate Elongation (%)	500	500

6. **Powder Content**	ASTM 6124	Below 10.0 mg/glove
7. **Protein Content**	ASTM 5712	Below 200 $\mu g/dm^2$

9. Conclusion

We concluded that the Blue Powdered Latex Examination Gloves, Protein Content Labeling (200 $\mu g/dm^2$ or less), Non-Sterile meets:

- ASTM D3578 Standard
- FDA pin hole requirement
- FDA minimum powder residual content
- CMDR requirement
- CGSB requirement
- Label Claim of 200 $\mu g/dm^2$ or less of total water extractable protein content

. Comparison table and discussion of the similarities and difference of Blue Powdered Latex :amination Gloves (Non-Sterile) compared to Multisafe Powdered Latex Examination Gloves, (Non-erile)

No	Description	Requirement	510K No	
			K993811	K062526
	Water Tight Test (1000ml)	GII,AQL 2.5	Pass GI, AQL 1.0	Pass GI , AQL 1.5
2	Dimension Test	Min. 290 (Long Glove) Min. 230 (Short Glove)	Min 230 for all sizes	Min 290 for all sizes
3	Palm Width (mm)	XS : 70 +/- 10 S : 80 +/- 10 M : 90 +/- 10 L :100 +/- 10	Meet the specification	Meet the specification
4	Thickness (mm) i) Finger ii) Palm	 Min. 0.08 Min. 0.08	Meet the specification	Meet the specification
5	Physical Properties (Before Aging) i) Tensile Strength (Mpa) ii) Ultimate Elongation (%) Physical Properties (After Aging) i) Tensile Strength (Mpa) ii) Ultimate Elongation (%)	 Min 14 Min. 700 Min. 14 Min. 500	 Min 18 Min. 700 Min. 14 Min. 500	 Min. 18 Min. 700 Min. 14 Min. 500
6	Powder Content	ASTM 6124	Meet the specification	Below 10.0mg/glove
7	Protein Content	ASTM 5712	Meet the specification	Below 200 $\mu g/dm^2$
8	Biocompatibility Test i) Primary Skin Irritation ii) Dermal Sensitization Assay (Animal Study)	 No Animal Irritation No Animal Irritation	 Yes Yes	 Yes Yes
9	Colour Extraction	Others	Normal Creamy White	Blue Colour
10	Ingredient a) Latex b) Accelerators c) Antioxidant d) Curing Agent e) Activator	 Natural Rubber latex ZDBC ZDEC Sulphur Zinc Oxide	 √ √ √ √ √	 √ √ √ √ √

	f) Dispersing Agent g) Filler / Pigment h) Donning Powder i) Pigment	Tamol Titanium Dioxide Modified Corn Starch Flexobrite Blue	√ √ √ X	√ √ √ √

Conclusion :

e Blue Powdered Latex Examination Gloves (Non-Sterile) is similar with Multisafe Powdered Latex Examination Gloves (Non-Sterile) except the dimension of length and colour extraction.

MULTISAFE SDN. BHD.

R ABD HADI HUSIN
(Plant Manager)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2007

Mr. Abd Hadi Bin Husin
Quality Management Representative/Plant Manager
Multisafe Sdn Bhd
Lot 764, Bidor Industrial Estate
35500 Bidor
Perak Darul Ridzuan
MALAYSIA

Re: K062526
Trade/Device Name: Blue Powdered Latex Examination Gloves, Non-Sterile
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: February 14, 2007
Received: March 19, 2007

Dear Mr. Husin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062526

Device Name: Blue powdered latex Examination Gloves, Non-sterile

Indications For Use:

Blue Powdered Latex Examination Gloves, Non-sterile is a disposable medical device made from natural rubber latex compound. It is intended to be worn on the hands as barrier against potentially infectious materials and other contamination.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda B Murphy MD

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